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By:

Susan M. Foley

Attorney Docket No. 020093-000010US



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

MICHAEL L. SALGALLER, et al.

Application No.: 09/854,248

Filed: May 11, 2001

For: METHOD TO INCREASE CLASS I
PRESENTATION OF
EXOGENOUS ANTIGENS BY
HUMAN DENDRITIC CELLS

Examiner: Unassigned

Art Unit: 1614

**INFORMATION DISCLOSURE
STATEMENT**

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

Applicants direct the Examiner's attention to the references below, also listed on the accompanying Form PTO-1449. A copy of each is also enclosed.

The following U.S. Patents are set forth below by issue date:

AA. U.S. Patent No. 5,162,504 issued on November 10, 1992 to

Horoszewicz.

AB. U.S. Patent No. 5,227,471 issued on July 13, 1993 to Wright, Jr.

AC. U.S. Patent No. 5,314,996 issued on May 24, 1994 to Wright, Jr.

AD. U.S. Patent No. 5,788,963 issued on August 4, 1998 to Murphy et al.

The following international publications are set forth by publication date:

AE. PCT Publication No. WO 94/02156 published on February 3, 1994.

AF. PCT Publication No. WO 98/15616 published on April 16, 1998.

The following articles are set forth by the indicated year of publication date:

AG. Poste et al., "Lipid Vesicles as Carriers for Introducing Biologically Active Materials into Cells," *Methods in Cell Biology*, 14:33-71 (1976).

AH. Haskill et al., "Systemic and Local Immunity in Allograft and Cancer Rejection," *Contemp. Top. Immunobiol.*, 8:107-170 (1978).

AI. Papsidero et al., "A Prostate Antigen in Sera of Prostatic Cancer Patients," *Cancer Res.*, 40:2428-2432 (July, 1980).

AJ. Okada et al., "Introduction to Macromolecules into Cultured Mammalian Cells by Osmotic Lysis of Pinocytic Vesicles," *Cell*, 29:33-41 (May, 1982).

AK. Horoszewicz et al., "The LNCaP Cell Line-A New Model for Studies on Human Prostatic Carcinoma," *Prog. Clin. Biol. Res.*, 37:115-132 (1983).

AL. Vose et al., "Human Tumor-Infiltrating Lymphocytes: A Marker of Host Response," *Semin. Hematol.*, 22:27-40 (January, 1985).

AM. Inaba et al., "Direct Activation of CD8⁺ Cytotoxic T Lymphocytes by Dendritic Cells," *J. Exp. Med.*, 166:182-194 (July, 1987).

AN. Macatonia et al., "Primary Stimulation by Dendritic Cells Induces Antiviral Proliferative and Cytotoxic T Cell Responses In Vitro," *J. Exp. Med.*, 169:1255-1264 (April, 1989).

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AP. Markowicz et al., "Granulocyte-Macrophage Colony-Stimulating Factor Promotes Differentiation and Survival of Human Peripheral Blood Dendritic Cells In Vitro," *J. Clin. Invest.*, 85:955-961 (March, 1990).

AQ. Young et al., "Dendritic Cells Stimulate Primary Human Cytolytic Lymphocyte Responses in the Absence of CD4⁺ Helper T Cells," *J. Exp. Med.*, 171:1315-1332 (April, 1990).

AR. Freudenthal et al., "The Distant Surface of Human Blood Dendritic Cells, as Observed after an Improved Isolation Method," *Proc. Natl. Acad. Sci. USA*, 87:7698-7702 (October, 1990).

AS. Beckett et al., "Monoclonal Antibody PD41 Recognizes an Antigen Restricted to Prostate Adenocarcinomas," *Cancer Res.*, 51:1326-1333 (February 15, 1991).

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AU. De Bruijn et al., "Peptide Loading of Empty Major Histocompatibility Complex Molecules on RMA-S Cells Allows the Induction of Primary Cytotoxic T Lymphocyte Responses," *Eur. J. Immunol.*, 21:2963-2970 (1991).

AV. Macatonia et al., "Primary Proliferative and Cytotoxic T-Cell Responses to HIV Induced *In Vitro* by Human Dendritic Cells," *Immunology*, 74:399-406 (1991).

AW. Reddy et al., "PH Sensitive Liposomes Provide an Efficient Means of Sensitizing Target Cells to Class I Restricted CTL Recognition of a Soluble Protein," *J. Immunol. Methods*, 141:157-163 (1991).

AX. Steinman, "The Dendritic Cell System and Its Roll in Immunogenicity," *Ann. Rev. Immunol.*, 9:271-296 (1991).

AY. Schwartz, "Costimulation of T Lymphocytes: The Role of CD28, CTLA-4, and B7/BB1 in Interleukin-2 Production and Immunotherapy," *Cell*, 71:1065-1068 (December 24, 1992).

AZ. De Bruijn et al., "Mechanisms of Induction of Primary Virus-Specific Cytotoxic T Lymphocyte Responses," *Eur. J. Immunol.*, 22:3013-3020 (1992).

BA. Pardoll, "New Strategies for Active Immunotherapy with Genetically Engineered Tumor Cells," *Curr. Opin. Immunol.*, 4:619-623 (1992).

BB. Inaba, et al., "Dendritic Cell Progenitors Phagocytose Particulates, Including Bacillus Calmette-Guerin Organisms, and Sensitize Mice to Mycobacterial Antigens *In Vivo*," *J. Exp. Med.*, 178:479-488 (August, 1993).

BC. O'Doherty et al., "Dendritic Cells Freshly Isolated from Human Blood Express CD4 and Mature into Typical Immunostimulatory Dendritic Cells after Culture in Monocyte-Conditioned Medium," *J. Exp. Med.*, 178:1067-1078 (September, 1993).

BD. Houbiers et al., "*In Vitro* Induction of Human Cytotoxic T Lymphocyte Responses Against Peptides of Mutant and Wild-Type p53," *Eur. J. Immunol.*, 26:2072-2077 (1993).

BE. Israeli et al., "Expression of the Prostate-Specific Membrane Antigen," *Cancer Res.*, 54:1807-1811 (April 1, 1994).

BF. Sallusto et al., "Efficient Presentation of Soluble Antigen by Cultured Human Dendritic Cells Is Maintained by Granulocyte/Macrophage Colony-Stimulating Factor Plus Interleukin 4 and Downregulated by Tumor Necrosis Factor α ," *J. Exp. Med.*, 179:1109-1118 (April, 1994).

BG. Romani et al., "Proliferating Dendritic Cell Progenitors in Human Blood," *J. Exp. Med.*, 180:83-93 (June, 1994).

BH. Bernhard et al., "Generation of Immunostimulatory Dendritic Cells from Human CD34+ Hematopoietic Progenitor Cells of the Bone Marrow and Peripheral Blood," *Cancer Res.*, 55:1099-1104 (March 1, 1995).

BI. McCormack et al., "Molecular Forms of Prostate-Specific Antigen and the Human Kallikrein Gene Family: An New Era," *Urology*, 45:729-744 (May, 1995).

BJ. De Bruijn et al., "Phagocyte-Induced Antigen-Specific Activation of Unprimed CD8⁺ T Cells," *Eur. J. Immunol.*, 25:1274-1285 (1995).

BK. Grey et al., "Class I MHC-Peptide Interactions: Structural Requirements and Functional Implications," *Cancer Surveys*, 22:37-49 (1995).

BL. Koch et al., "Antigen Processing in Populations of Mature Murine Dendritic Cells Is Caused by Subsets of Incompletely Matured Cells," *J. Immunol.*, 155:93-100 (1995).

BM. Hsu et al., "Vaccination of Patients with B-Cell Lymphoma Using Autologous Antigen-Pulsed Dendritic Cells," *Nat. Med.*, 2:52-58 (January, 1996).

BN. Su et al., "Surface-Epitope Masking and Expression Cloning Identifies the Human Prostate Carcinoma Tumor Antigen Gene PCTA-1 a Member of the Galectin Gene Family," *Proc. Natl. Acad. Sci. USA*, 93:7252-7257 (July, 1996).

BO. Jondal et al., "MHC Class I-Restricted CTL Responses to Exogenous Antigens," *Immunity*, 5:295-302 (October, 1996).

BP. Murphy et al., "Phase I Clinical Trial: T-Cell Therapy for Prostate Cancer Using Autologous Dendritic Cells Pulsed with HLA-A0201-Specific Peptides from Prostate-Specific Membrane Antigen," *Prostate*, 29:371-380 (1996).

BQ. Cella et al., "Inflammatory Stimuli Induce Accumulation of MHC Class II Complexes on Dendritic Cells," *Nature*, 388:782-787 (August, 1997).

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BT. Thurnher et al., "Bacillus Calmette-Guerin Mycobacteria Stimulate Human Blood Dendritic Cells," *Int. J. Cancer*, 70:128-134 (1997).

BU. Reiter, et al., "Prostate Stem Cell Antigen: A Cell Surface Marker Overexpressed in Prostate Cancer," *Proc. Natl. Acad. Sci. USA*, 95:1735-1740 (February, 1998).

BV. Banchereau et al., "Dendritic Cells and the Control of Immunity," *Nature*, 392:245-252 (March, 1998).

BW. Nestle et al., "Vaccination of Melanoma Patients with Peptide- or Tumor Lysate-Pulsed Dendritic Cells," *Nat. Med.*, 4:328-332 (March, 1998).

BX. Ramoner et al., "Activation of Human Dendritic Cells by Bacillus Calmette-Guerin," *J. Urology*, 159:1488-1492 (May, 1998).

BY. Fields et al., "Murine Dendritic Cells Pulsed with Whole Tumor Lysates Mediate Potent Antitumor Immune Responses *In Vitro* and *in Vivo*," *Proc. Natl. Acad. Sci. USA*, 95:9482-9487 (August, 1998).

BZ. Salgaller, et al., "Report of Immune Monitoring of Prostate Cancer Patients Undergoing T-Cell Therapy Using Dendritic Cells Pulsed with HLA-A2-Specific Peptides from Prostate-Specific Membrane Antigen (PMSA)," *Prostate*, 35:144-151 (1998).

CA. Steel et al., "Helminth Antigens Selectively Differentiate Unsensitized CD45RA⁺CD4⁺ Human T Cells in Vitro," *J. Immunol.*, 160:351-360 (1998).

CB. Hubert et al., "STEAP: A Prostate-Specific Cell-Surface Antigen Highly Expressed in Human Prostate Tumors," *Proc. Natl. Acad. Sci. USA*, 96:14523-14528 (December 7, 1999).

CC. Murphy et al. "Phase II Prostate Cancer Vaccine Trial: Report of a Study Involving 37 Patients with Disease Recurrence Following Primary Treatment," *Prostate*, 39:54-59 (1999).

It is respectfully requested that the cited information be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

Applicants believe that their invention as claimed is patentable over the above references taken alone or in any combination. However, Applicants reserve the right to demonstrate that their claimed invention was made prior to any one or more of the above-identified references. No inference should be drawn as to the pertinence of the references based on the order in which they are presented.

Applicants respectfully request that the Examiner review the foregoing references to make his own determination of the patentability of the present invention and that the references be made of record in the file of this application.

This Information Disclosure Statement is being filed prior to the mailing date of the first Office Action. Although no fee is believed to be due, the Commissioner is hereby authorized to charge any fees necessitated by this transmittal to Townsend and Townsend Deposit Account No. 20-1430.

Respectfully submitted,

Dated: 17 January 2002

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